

REMARKS

I. Status and Disposition of the Claims

Prior to this amendment, claims 7, 10, and 20-26 were pending. By the above amendment, claims 7, 20 and 21 are amended, and claim 10 is cancelled. Thus, claims 7 and 20-26 are now pending and under consideration on the merits.

Claim 7 has been amended to incorporate the easily diffusable elements recited by previous claim 10, with the exception of carbon. Claims 20 and 21 have been amended so as to depend from a pending claim. Support for the amended claims can be found in the specification and claims as originally filed. No new matter has been added.

Applicants acknowledge, with appreciation, the Examiner's withdrawal of the prior rejection of claims 7, 10, and 20-26 under 35 U.S.C. §112, second paragraph. However, the Examiner continues to reject claims 7, 10 and 22-26 under 35 U.S.C. §102(b) as alleged anticipated by Japanese Patent Application Publication No. JP 04 187159 (Yamauchi et al.). Office Action, page 2. In addition, the Examiner rejects claims 7, 10 and 22-26 under 35 U.S.C. §102(e) as being allegedly anticipated by U.S. Patent No. 6,325,766 ("Anderson"). *Id.* at 2-3. Finally, the Examiner rejects claims 7, 10, 20, 21, 23 and 24 under 35 U.S.C. §103(a) as being allegedly unpatentable over Anderson in view of U.S. Patent No. 5,722,981 ("Stevens"). Applicants respectfully disagree with and traverse each of these rejections for at least the following reasons.

II. Response to Rejections

a. The §102(b) rejection of claims 7, 10 and 20-26 in view of Yamauchi is improper

The Examiner maintains that Yamauchi anticipates each and every element of claims 7, 10 and 22-26. Office Action, page 2. Applicants respectfully continue to disagree with the Examiner's position for at least the reasons of record. However, to advance prosecution, Applicants have amended claim 7 so as to incorporate the easily diffusable elements of previous claim 10, with the exception of carbon. Accordingly, claim 10 has been cancelled. Thus, the §102(b) rejection of claim 10 is moot. With respect to pending claims 7 and 22-26, Applicants respectfully disagree with and traverse this rejection for at least the following reasons.

To establish the anticipation of a claim, the Examiner must show that each element of the claim at issue is found, either expressly or under the principles of inherency, in a single prior art reference. *Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 24 U.S.P.Q.2d 1321 (Fed. Cir. 1992) (emphasis added). Further, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989) (citations omitted). See *also* M.P.E.P. § 2131.

Present claim 7 recites:

An elongated device for medical procedures comprising a superelastic member having a first section with a first set of properties and an adjacent second section having a second set of properties which have been altered from the first set of properties by alloying the second section with an easily diffusable element, wherein said easily diffusable element is selected from

the group consisting of oxygen, hydrogen, and nitrogen, and the superelastic member comprises a nickel-titanium alloy.

Unlike claim 7, Yamauchi does not teach, *inter alia*, an elongated device for medical procedures comprising a second section having easily diffusable element selected from oxygen, hydrogen, or nitrogen, as claimed.

As Yamauchi does not teach each and every element of claims 7 and 22-26, Applicants submit that the §102(b) rejection of these claims is improper, and ask that it be withdrawn.

b. The §102(e) rejection of claims 7, 10 and 22-26 in view of Anderson is improper

The Examiner has maintained the rejection of claims 7, 10 and 22-26 under §102(e) as allegedly anticipated by Anderson. Office Action, pages 2-3. The rejection of claim 10 is moot in view of the amendment. With respect to pending claims 7 and 22-26, Applicants disagree with and traverse this rejection for at least the following reasons.

The Examiner asserts that “Anderson... disclose[s] a superelastic member having a first section (14) with a first set of properties and an adjacent second section (12) having a second set of properties which have been altered from the first set of properties by alloying the second section with an easily diffusable element...” Office Action, page 2. Applicants respectfully disagree.

Anderson discloses a guidewire (10) having an elongated proximal portion (12) including a distal end (13) and a distal portion (14). Anderson, column 2, lines 13-18 and 38-45. Distal end (13) is formed from a “substantially nickel-free high-nitrogen

austenitic stainless steel alloy” (which is not superelastic). *Id.* Distal portion (14) is made from a “pseudo- or super-elastic [alloy]... such as nickel-titanium alloys.” *Id.* In the alternative, Anderson discloses that both distal end (13) and distal portion (14) may be manufactured from stainless steel. *Id.* at lines 53-62.

Anderson, however, does not disclose an elongated device for medical procedures comprising, *inter alia*, “a superelastic member having a first section with a first set of properties and an adjacent second section with a second set of properties[,]” as claimed, as recited in claim 7. That is, Anderson does not teach an elongated member having two adjacent superelastic sections, much less two adjacent superelastic portions wherein one portion exhibits altered properties as a result of being alloy with an easily diffusable element selected from oxygen, nitrogen, or hydrogen, as claimed. Rather, as mentioned above, Anderson disclose a guidewire having a distal end (13) (first section) comprising austenitic stainless steel (which is not superelastic) and an adjacent distal portion (14) manufactured from either superelastic NiTi containing carbon or stainless steel. Anderson, column 2, lines 13-18, 38-45 and 53-62.

For at least the foregoing reasons, Anderson does not teach each and every element of pending claims 7 and 22-26. Therefore the rejection of these claims under 35 U.S.C. §102(e) as allegedly anticipated by Anderson is improper, and should be withdrawn.

c. The §103(a) rejection of claims 7, 10, 20, 21, 23 and 24 in view of Anderson and Stevens is improper.

The Examiner has also maintained the rejection of claims 7, 10, 20, 21, 23 and 24 under §103(a) as allegedly unpatentable over Anderson in view of Stevens. Office Action, pages 3-4. The rejection of claim 10 is moot in view of the above amendment. With respect to pending claims 7, 20, 21, 23 and 24, Applicants disagree with and traverse this rejection for at least the following reasons.

According to the Examiner, it would have been obvious to one of ordinary skill in the art at the time the invention was made to “modify the distal section as disclosed by Anderson et al. to include a nickel-titanium alloy which has been alloyed with an easily diffusible element as taught by Stevens et al. in order to allow the medical device to have a pre-formed shape, be stressed into another shape, and then return to its pre-formed shape” Office Action, pages 3-4. Applicants respectfully disagree for at least the following reasons.

In order to carry the initial burden of establishing a prima facie case of obviousness, the Examiner must show that the relied upon prior art references teach or suggest all of the elements of a claim. See M.P.E.P. § 2143. In addition, there must be some teaching or suggestion that would have motivated one of ordinary skill in the art to modify the references so as to arrive at the claimed invention. See M.P.E.P. § 2143.

First, although Stevens may teach various alloy additions to NiTi, Stevens does not correct Anderson's failure to teach an elongated member having two adjacent superelastic sections, much less two adjacent superelastic portions wherein one portion exhibits altered properties as a result of being alloy with an easily diffusible element

selected from oxygen, nitrogen, or hydrogen, as claimed. Thus, even if, *arguendo*, one of ordinary skill in the art would have been motivated to combine Anderson with Stevens in the manner suggested by the Examiner, the resulting combination would still fail to teach or suggest each and every element of at least claim 7.

Second, Applicants submit that there is no teaching or suggestion in the cited references that would have motivated one of ordinary skill in the art to modify Anderson with Stevens in the manner asserted. Admittedly, Stevens mentions alloying NiTi with various additional elements, including oxygen and hydrogen. However, neither Stevens nor Anderson, alone or in combination, provide any indication as to *why* NiTi alloyed with oxygen and or hydrogen would be beneficially used in Anderson's guidewire. Indeed, neither Anderson nor Stevens provide any indication that NiTi alloyed with oxygen and/or hydrogen would function in an equivalent, much less superior degree to the alloys utilized in Anderson's guidewire.

Moreover, the motivation proposed by the Examiner - "in order to allow the medical device to have a per-formed shape, be stressed into another shape, and then return to it original shape" - is ineffectual. Office Action, pages 3-4. Any superelastic NiTi alloy, if formed into a medical device, will allow the medical device to function in the manner asserted by the Examiner as motivation. That is, all superelastic NiTi alloys are capable of: a) having a pre-formed shape; b) being stressed into another shape; and c) returning to their original shape from the stressed shape. One of ordinary skill in the art would be aware of this fact, and therefore would not be motivated to substitute Stevens' alloy for the alloy utilized in Anderson based solely upon this proffered similarity.

For at least the foregoing reasons, Anderson and Stevens, alone or in combination, fail to teach or suggest each and every element of claims 7, 20, 21, 23 and 24 under §103(a) as being allegedly unpatentable over Anderson in view of Stevens is improper, and should be withdrawn.

III. Conclusion

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 7 and 20-26 in condition for allowance.

Applicants submit that the proposed amendments to claims 7, 20 and 21 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Applicants further submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that the claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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